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PO BOX 747	CH 3/A 22040 0747	SZNAIDMAN, MARCOS L		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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	Application No.	Applicant(s)			
	10/519,999	AMMERMANN ET AL.			
Office Action Summary	Examiner	Art Unit			
	MARCOS SZNAIDMAN	1611			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status					
Responsive to communication(s) filed on <u>05 Ja</u> This action is FINAL . 2b)⊠ This Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro				
Disposition of Claims					
4) ☐ Claim(s) 1-8 is/are pending in the application. 4a) Of the above claim(s) is/are withdrav 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-8 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or Application Papers 9) ☐ The specification is objected to by the Examine 10) ☐ The drawing(s) filed on is/are: a) ☐ access	r election requirement. r.	≣xaminer.			
Applicant may not request that any objection to the orection Replacement drawing sheet(s) including the correction The oath or declaration is objected to by the Ex	ion is required if the drawing(s) is obj	ected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 3 pages / 01/05/05.	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ate			

DETAILED ACTION

This office action is in response to applicant's filing of January 5, 2005.

Status of Claims

Claims 1-8 are currently pending and are the subject of this office action.

Claims 1-8 are presently under examination.

Priority

The present application is a 371 of PCT/EP03/06891 filed on 06/30/2003, and claims priority to foreign application: GERMANY 10233520.6 filed on 07/23/2002.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 8 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 provides for the use of "the compounds of formula I and II for preparing a mixture as in claim 1", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for controlling *Plasmopara viticola* in grapevines and *Phytophthora infestans* in tomatoes, does not reasonably provide enablement for all other phytopathogenic fungi. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the

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invention commensurate in scope with these claims. This is a scope of enablement rejection.

To be enabling, the specification of the patent application must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1561 (Fd. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated that:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996). As pointed out by the court in *In re Angstadt*, 537 F.2d 498 at 504 (CCPA 1976), the key word is "undue", not "experimentation".

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 wherein, citing *Ex parte Forman*, 230 USPQ 546 (Bd. Apls. 1986) at 547 the court recited eight factors:

- 1- the quantity of experimentation necessary,
- 2- the amount of direction or guidance provided,
- 3- the presence or absence of working examples,
- 4- the nature of the invention,
- 5- the state of the prior art,
- 6- the relative skill of those in the art,
- 7- the predictability of the art, and
- 8- the breadth of the claims

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These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. *In re Fisher*, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the *Wands* factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention

Claims 5-7 recite a method for controlling harmful fungi, which comprises treating harmful fungi with a fungicidal mixture comprising compound I and compound II, in a synergistically effective amount.

2. The state and predictability of the art

Synergistic effects for combination of compounds are highly unpredictable. In fact there are no examples in the literature where two compounds that are biologically active against one target were predicted to act in a synergistic form. So far, the only way to determine synergy between two or more active substances is experimentally.

3. The relative skill of those in the art

The relative skill is generally that of an M.S. or Ph.D. in agrochemical sciences.

4. The breadth of the claims

Claims 5-7 claim to control every type of fungi with the mixtures of claim 1.

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 The amount of direction or guidance provided and the presence or absence of working examples

The specification provides data for controlling *Plasmopora viticola* in grapevine (see page 8) and *Phytophthora infestans* in tomatoes (see page 7). The specification provides no direction or guidance for controlling any other type of fungi.

6. The quantity of experimentation necessary

In the absence of previous examples in the prior art and in the absence of experimental evidence commensurate with the scope of the claims, how is the skilled in the art supposed to know which proportions of each compound to use for each type of fungi? This would require determining the optimum ratio and absolute amounts of compounds I and II, formulation into a dosage form, and subjecting into testing. This is undue experimentation given the limited guidance and direction provided by Applicants.

Accordingly, the inventions of claims 5-7 do not comply with the scope of enablement requirement of 35 U.S.C 112, first paragraph, since to practice the claimed invention a person of ordinary skill in the art would have to engage in undue experimentation with no assurance of success.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dehne et. al. (US 5,491,165).

Claims 1 and 2 recite a fungicidal mixture comprising: 1) at least on valinamide derivative of the formula I (specifically la when R is F) and 2) the compound of formula II (dithianon) in a synergistically effective amount.

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For claims 1 and 2, Dehne et. al. teach a fungicidal mixture comprising: 1) valinamide derivatives of formula I (see abstract and column 1, first structure) and 2) dithianon (see column 2, last structure).

Although Dehne et. al. do not disclose the valinamide compound of the instant application (Ia, see instant claim 2), at the time of the invention, it would have been *prima facie* obvious for a person of ordinary skill in the art to combine any valinamide derivative, including the instant claimed compound Ia, with dithianon, because it will be obvious to try (i.e. choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success, see MPEP 2142, section III), thus resulting in the practice of claims 1-2 with a reasonable expectation of success.

Claim 3, recites the same limitations as claim 1 or 2, wherein the weight ratio between compound I (a valinamide derivative) and dithianon is from 10:1 to 1:100.

For claim 3, Dehne et. al. further teach that the weight ratio of a valinamide derivative of formula I and dithianon of 1:1 to 1:50 (see column 6, lines 42-43).

At the time of the invention, it would have been *prima facie* obvious for a person of ordinary skill in the art to combine a valinamide derivative of formula I, and dithianon in a ratio as thought by Dehne et. al., thus resulting in the practice of claim 3 with a reasonable expectation of success.

Claim 4, recites the same limitations as claim 1, wherein the mixture further comprises a liquid or solid carrier.

For claim 4, Dehne et. al further teach that the compounds can be co-formulated with carriers and or additives known in the art (see column 7, lines 26-30).

At the time of the invention, it would have been *prima facie* obvious for a person of ordinary skill in the art to co-formulate a valinamide derivative of formula I and dithianon with carriers as thought by Dehne et. al., thus resulting in the practice of claim 4 with a reasonable expectation of success.

Claim 5 recites a method for controlling harmful fungi, which comprises treating fungi with an effective amount of 1) at least on valinamide derivative of the formula I (see claim 1) and 2) the compound of formula II (dithianon) in a synergistically effective amount.

For claim 5, Dehne et. al. teach a method of treating *Plasmopara viticola* in grapevines and *Phytophthora infestans* in tomatoes (see column 7, lines 11-14), with a fungicidal mixture comprising: 1) valinamide derivatives of formula I (see abstract and column 1, first structure) and 2) dithianon (see column 2, last structure) in a synergistically effective amount (see column 4, lines 55-60).

Although Dehne et. al. do not disclose the valinamide compound of the instant application (formula I in instant claim 1), at the time of the invention, it would have been prima facie obvious for a person of ordinary skill in the art to combine any valinamide

derivative, including the instant claimed compound: Ia, with dithianon, because it will be obvious to try (i.e. choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success, see MPEP 2142, section III), and further use the mixture to treat *Plasmopara viticola* in grapevines and *Phytophthora infestans* in tomatoes, thus resulting in the practice of claim 5 with a reasonable expectation of success.

Claims 6 and 7 recite the same limitations as claim 5, wherein the valinamide derivative of structure I is applied in an amount of from 5 g/ha to 500 g/ha (claim 6) and wherein dithianon is applied in an amount of from 5 g/ha to 2000 g/ha (claim 7).

Although, Dehne et. al. do not teach the specific amounts of valinamide derivative and dithianon to be applied, it's within the capability of the ordinary artisan to determine these amounts for a particular crop and adjust dosage amounts based on the observed effectiveness, thus resulting in the practice of claims 6 and 7 with a reasonable expectation of success.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MLS April 23, 2008 /MP WOODWARD/ Supervisory Patent Examiner, Art Unit 1615